OCT 1 6 2001

**Thermo** DMA

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## 510 (k) Summary

This Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**Submitter:** Thermo DMA, Inc.

**Address:** 845 Avenue G East
Arlington, Texas 76011

**Contact Person:** Thomas Dollar, Manager of Regulatory Affairs

**The assigned 510(k) number is** K012878

**Product Code:** JIS, Calibrator, primary

**Device Name:** Thermo Trace Ammonia Standards Set

**Device Class:** II

**Description and Intended Use:** The Thermo Trace Ammonia Standards are aqueous (ammonia free deionized water) solutions of Ammonium Sulfate (Merck GR ACS ISO Catalog Number 10127) with preservative (Sodium Azide). The Thermo Trace Ammonia Standard set is intended for in vitro diagnostic use with Thermo Trace Ammonia Reagent (K974620) to establish points of reference that are used in the determination of Ammonia in human plasma.

**Storage and Stability:** Product stability was determined by performing accelerated stability studies as per Thermo Trace's product stability Standard Operating Procedure (SOP). The standards were stressed at three temperatures (minimum) for a pre-defined period of time, and then tested to ensure that stressed standards continue to meet performance specifications. Based on the results of these studies, a shelf life for the product is set. Real time testing is then conducted to further validate the established dating. For the ammonia standards, real-time stability data collection is ongoing.

**Value Assignment and Validation:** Values are assigned by gravimetric composition. The specified amount of Anhydrous Ammonium Sulfate is accurately weighed on a calibrated analytical balance and dissolved in a Class A volumetric flask with ammonia free deionized water (<1 micromole/Liter).

The values of the standards are confirmed in accordance with the Thermo Trace Ammonia Standard Production Specification document number PS345/00. Each lot of standard is tested with Thermo Trace Ammonia DST reagent, using a previously approved standard lot as a control. Commercially available controls (Roche Preciset $NH_3$) are also included in the verification assay to serve as additional controls on the accuracy of the standard material on an ongoing basis. The product specification #PS3435/00 is also included here for reference.

**Instrument Application:** Analytical use of the Cobas Mira in testing this product(s) is described in procedure number PS345/00.

**Date of Preparation August 23, 2001**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 1 6 2001

Mr. Thomas Dollar
Manager of Regulatory Afffairs
Thermo DMA
845 Avenue G East
Arlington, TX 76011-7709

Re: k012878
Trade/Device Name: Thermo Trace Ammonia Standards Set
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIS
Dated: August 24, 2001
Received: August 28, 2001

Dear Mr. Dollar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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## INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K012878

Device Name: Thermo Trace Ammonia Standards Set

Indications For Use: This reagent is intended for use with Thermo Trace Ammonia Reagent(510(k) number K(74620) to establish points of reference that are used in the determination of Ammonia in human plasma.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Kesia Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012878

✓ Prescription Use OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

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